JUL 27 2005

C. 510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

[in Accordance with SMDA of 1990]

S4 Spinal System

April 18, 2005

COMPANY: Aesculap®, Inc.
3773 Corporate Parkway
Center Valley, PA 18034

Establishment Registration Number: 2916714

CONTACT: Joyce Kilroy
800/258-1946 x 5074 (phone)
610/791-6882 (fax)

TRADE NAME: S4

COMMON NAME: S4 Spinal System

DEVICE CLASS: Class II

PRODUCT CODE: MNI, KWP

CLASSIFICATION: 888.3070 – Pedicle screw spinal system

888.3050 – Spinal interlaminal fixation orthosis

REVIEW PANEL: Orthopedics

INDICATIONS FOR USE

When intended to promote fusion of the cervical spine and the thoracic spine (C1 – T3), the S4 Spinal System is intended for the following;

- DDD (Neck pain pf discogenic origin with degeneration of the disc as confirmed by patient history and radiographic studies)
- Spondylolisthesis
- Spinal stenosis
- Fracture/dislocation
- Failed previous fusion
- Tumors

The hooks and rods are also intended to provide stabilization to promote fusion following reduction of fracture/dislocation or trauma in the cervical/upper thoracic (C1 – T3) spine.

The use of the polyaxial screws is limited to placement in T1 – T3 in treating thoracic conditions only. Screws are not intended to be placed in the cervical spine.

DEVICE DESCRIPTION

The S4 Spinal System consists of 3.5mm rods in 6 lengths, thin and thick lamina hooks, 3.5 and 4.0mm polyaxial screws of various lengths and a cross connector. The S4 Spinal System is manufactured from Titanium forged alloy Ti6Al4V.

PERFORMANCE DATA

All required testing per "Draft Guidance for the Preparation of Premarket Notifications (510(k)s) Applications for Orthopedic Devices-The Basic Elements" were done where applicable. In addition, testing per the "Spinal System 510(k)s" was completed where applicable.

SUBSTANTIAL EQUIVALENCE

Aesculap believes that the new S4 Spinal System is substantially equivalent in design to:

- Nex- Link Spinal System (K031985)
- Vertex Spinal System (K042789, 042524)
- Summit Spinal System (K013222, K030103, K041203)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 27 2005

Ms. Joyce Kilroy
Director of Regulatory Affairs/Quality Assurance
Aesculap, Inc.
3773 Corporate Parkway
Center Valley, Pennsylvania 18034

Re: K050979
Trade/Device Name: S4 Spinal System
Regulation Number: 21 CFR 888.3050, 21 CFR 888.3070
Regulation Name: Spinal interlaminal fixation orthosis, Pedicle screw spinal system
Regulatory Class: II
Product Code: KWP, MNI
Dated: July 20, 2005
Received: July 21, 2005

Dear Ms. Kilroy:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

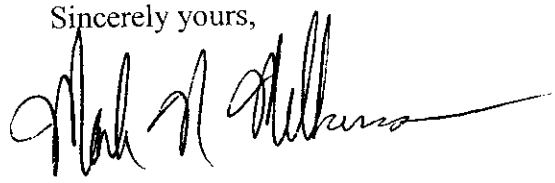
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Mark N. Melkerson
Acting Director
Division of General, Restorative,
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

B. INDICATIONS FOR USE STATEMENT

510(k) Number: K050979

Device Name: **S4 Spinal System**

Indication for Use:

When intended to promote fusion of the cervical spine and the thoracic spine (C1 – T3), the S4 Spinal System is intended for the following;

- DDD (Neck pain pf discogenic origin with degeneration of the disc as confirmed by patient history and radiographic studies)
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(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K050979

Prescription Use X or Over-the-Counter Use _____

(per 21 CFR 801.109)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)